

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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[Docket No. 2004N-0046]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, **Desk** Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drug Products — (OMB Control Number 0910–0167)—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an “open protocol” basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, **FDA** may require results of studies to be submitted for review. Section **316.14** contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application, which includes requirements that an applicant document that the disease is rare (affects fewer

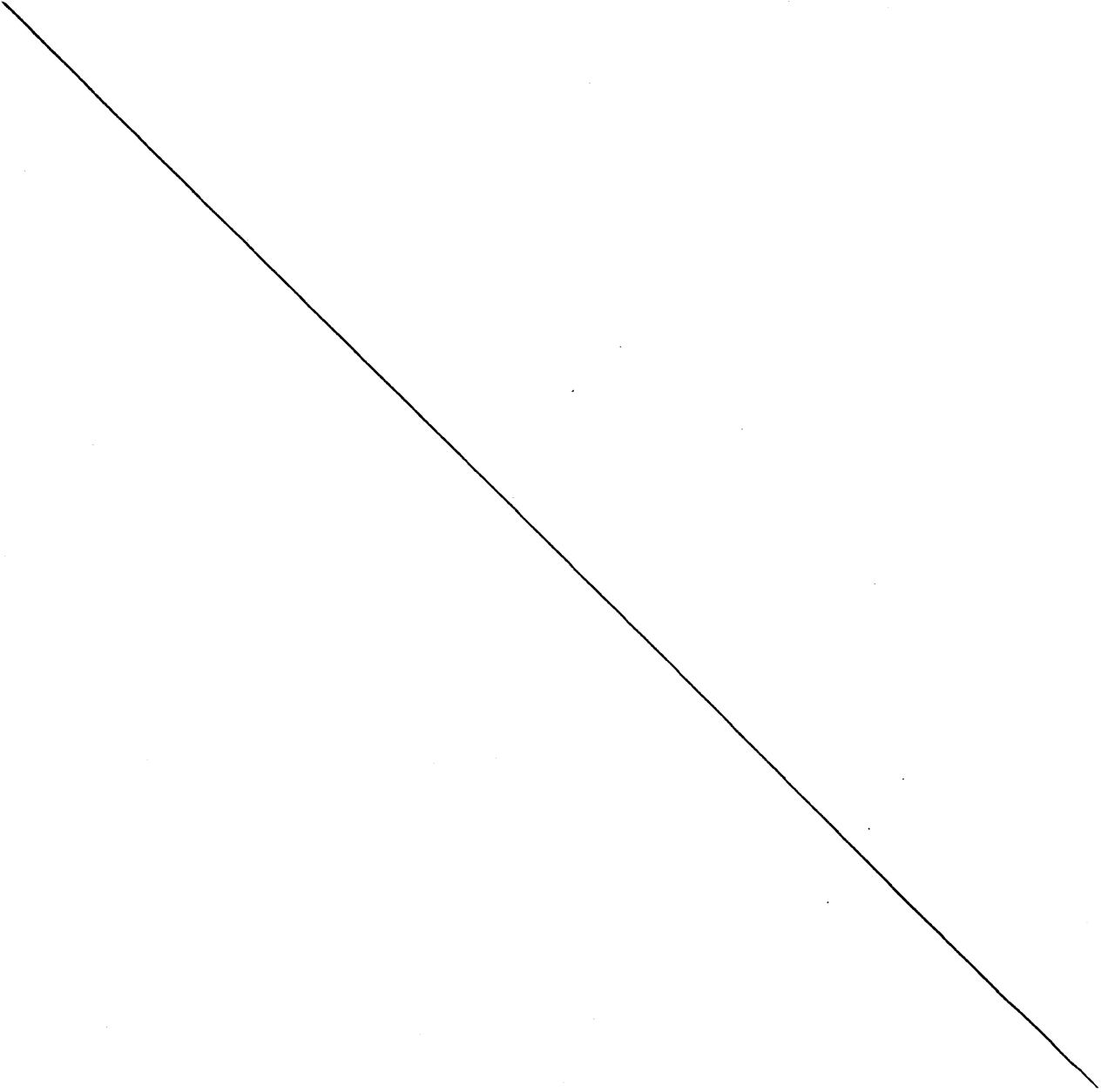
than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section **316.26** allows an applicant to amend the application under certain circumstances. Section **316.30** requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

In the **Federal Register** of February 24, **2004 (69 FR 8447)** FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

21 CFR Section	No. of Respondents	Annual Frequency of response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	3	1	3	130	390
316.20, 316.21, and 316.26	138	2.0	276	130	35,880
316.22	22	1	22	2	44
316.27	5	1	5	4	20
316.30	500	1	500	2	1,000
316.36	.2	3	.6	15	9
Total					37,343

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past **13** years that **138** persons or organizations per year will request orphan drug designation and

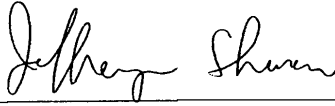
that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections **525** and **526** of the act (§§ **316.10**, **316.12**, **316.20**, and **316.21**) is generally similar and is estimated *to* require an average of 95 hours of professional staff time and **30** hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor



nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: 5.21.04

May 21, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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